

§ 1.234

21 CFR Ch. I (4–1–14 Edition)

(a) Fax number and e-mail address of the facility;

(b) Preferred mailing address, if different from that of the facility;

(c) Fax number and e-mail address of the parent company, if the facility is a subsidiary of the parent company;

(d) For a domestic facility, emergency contact name, title, and e-mail address;

(e) For a foreign facility, an emergency contact name, title, phone number and e-mail address. FDA will consider the facility's U.S. agent the facility's emergency contact unless the facility chooses to designate another person to serve as an emergency contact under this section;

(f) For a foreign facility, title, fax number, and e-mail address of the U.S. agent;

(g) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);

(h) Food categories not identified in §170.3 of this chapter, which are provided in Form 3537 sections 11a (e.g., infant formula, animal byproducts and extracts) and 11b (e.g., grain products, amino acids);

(i) Type of storage, if the facility is primarily a holding facility;

(j) A food product category of "most/all human food product categories," if the facility manufactures/processes, packs, or holds foods in most or all of the categories identified in §170.3 of this chapter;

(k) Approximate dates of operation, if the facility's business is seasonal;

(l) The fax number and e-mail address of the owner, operator, or agent in charge; and

(m) The fax number and e-mail address of the individual who authorized submission of the registration.

§ 1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* The owner, operator, or agent in charge must submit an update to a facility's registration within 60 calendar days of any change to any of the information previously submitted under §1.232 (e.g., change of operator, agent in charge, or U.S. agent), except a change of the owner. The owner, operator, or agent

in charge may authorize an individual to update a facility's registration.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in §1.235 within 60 calendar days of the change and the new owner must re-register the facility as specified in §1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at <http://www.fda.gov/furl>s.

(2) Once you complete your electronic update, FDA will automatically provide you with an electronic confirmation of your update.

(3) Your registration will be considered updated once FDA transmits your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in §1.231(a), you may update your facility's registration by mail or by fax:

(1) You must update your registration using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting the form by phone at 1-877-FDA-3882 (1-877-332-3882).

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-436-2804 or

1-800-573-0846.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax).

(4) FDA will enter complete and legible updates into its registration system, along with CD-ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(7) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

(e) *Update by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under §1.231(a), you may update your facilities' registrations by CD-ROM.

(1) Registrants submitting their updates in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) Update files must be submitted on a PDF rendition of FDA's registration form (Form 3537) and be accompanied by one signed copy of the certification statement on the registration form (Form 3537).

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD-ROM may contain updates for as many facilities as needed up to the CD-ROM's capacity.

(5) The update for each facility on the CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives an update CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM update submissions into its registration system, along with the complete and legible mailed and faxed update submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the update(s) as entered and confirmation of the update.

(10) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(11) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

[68 FR 58960, Oct. 10, 2003 as amended at 73 FR 15883, Mar. 26, 2008]

§ 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* A facility canceling its registration must do so within 60 calendar days of the reason for cancellation (*e.g.*, facility ceases operations, ceases providing food for consumption in the United States, or the facility is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and e-mail address (if available) of the individual submitting the cancellation; and

(5) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at <http://www.fda.gov/furls>.

(2) Once you complete your electronic cancellation, FDA will automatically provide you with an electronic confirmation of your cancellation.

(3) Your registration will be considered cancelled once FDA transmits your cancellation confirmation.

(d) *Cancellation by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of